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### The Story of Diamond v. Chakrabarty: Technological Change and the Subject Matter Boundaries of the Patent System

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#### Publication Information & Recommended Citation

Eisenberg, Rebecca S. "The Story of Diamond v. Chakrabarty: Technological Change and the Subject Matter Boundaries of the Patent System." In *Intellectual Property Stories*, edited by J. C. Ginsburg and R. C. Dreyfuss, 327-57. New York: Foundation Press, 2006.

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**FOUNDATION  
PRESS**

**INTELLECTUAL  
PROPERTY STORIES**

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**FOUNDATION PRESS**  
2006

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## Responses to Technological Change

### **The Story of *Diamond v. Chakrabarty*: Technological Change and the Subject Matter Boundaries of the Patent System**

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**Rebecca S. Eisenberg\***

Technological change often exposes unstated assumptions lurking in the law and makes them problematic, and patent law is no exception. Although the core mission of the patent system is to promote technological progress, path-breaking new technologies have not always been easily assimilated within its boundaries. The first wave of patent applications on advances in biotechnology in the 1970s illustrate some of the difficulties. Before that time, living organisms had generally been assumed to fall outside the range of patent-eligible subject matter under a time-honored exclusion for “products of nature.”<sup>1</sup> But genetically engineered organisms, although derived from naturally occurring life forms, seemed to involve too much human intervention to be characterized as natural products. Were they eligible for patent protection? Should the default rule be protection or no protection? What are the roles of the courts, the Patent and Trademark Office (PTO), and the legislature in figuring it out?

The first stop for inventors seeking patent rights in new technologies, and thus the first institution to confront the legal issues that these technologies raise, is the PTO. In the 1970s, as Ananda Chakrabarty’s patent application on a genetically modified, oil-eating bacterium worked its way through the system, the PTO was confronting growing numbers of patent applications in emerging “high technology” fields, notably

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\* © 2005 Rebecca S. Eisenberg. I am grateful to Rochelle Dreyfuss, Jane Ginsburg, and Daniel Kevles for helpful comments on earlier versions of this paper.

<sup>1</sup> See *Funk Bros. Seed v. Kalo Inoculant*, 333 U.S. 127 (1948).

information technology and biotechnology, that strained the capacities of its existing corps of examiners. Examination of patent applications in new fields always presents special administrative challenges, including a lack of examiners with the appropriate technical training and a lack of readily accessible prior art in the form of previously issued patents.<sup>2</sup> These challenges were particularly daunting in the days before examiners had access to commercial databases of prior art or even to personal computers. In this environment, the PTO had a strong institutional incentive to exclude these fields categorically from patent eligibility pending explicit legislation providing for their protection. Categorical exclusions offer an efficient mechanism for filtering out patent applications at the threshold of the PTO, without the need for examiners to delve into the underlying technology and to compare the claimed inventions to the prior art. If Congress thought that patent protection was appropriate, it could address the resource needs of the PTO at the same time that it considered what additional legislation was necessary for these fields.

On its face, the Patent Act extends protection to “any new and useful process, machine, manufacture or composition of matter,” without explicit subject matter exclusions.<sup>3</sup> But over the years the courts and the PTO have sometimes seemed to endorse exclusions from patent eligibility for certain categories of inventions, including architectural designs,<sup>4</sup> medical and surgical techniques,<sup>5</sup> plants,<sup>6</sup> agricultural methods,<sup>7</sup>

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<sup>2</sup> See generally Bhaven N. Sampat, *Examining Patent Examination: An Analysis of Examiner and Applicant Generated Prior Art*, NBER Working Papers (Aug. 2004 draft) (concluding on basis of empirical examination of prior art references cited by examiners and applicants that examiners are far better at identifying prior art in U.S. patents than they are at searching non-patent prior art or foreign patents, and that examiners face particular challenges in identifying prior art in emerging technological fields).

<sup>3</sup> 35 U.S.C. § 101.

<sup>4</sup> See, e.g., *Jacobs v. Baker*, 74 U.S. (7 Wall) 295 (1869) (suggesting that improvements in the construction of jails were not patent-eligible subject matter, although also noting that patents were properly invalidated for lack of novelty).

<sup>5</sup> *Morton v. New York Eye Infirmary*, 17 F. Cas. 879 (S.D.N.Y. 1862) (No. 9865) (holding ineligible for patent protection method of performing surgery by applying ether to render patient insensitive to pain); *Ex parte Brinkerhoff*, 24 Dec. Comm’n Pat. 349 (1883) (holding that “the methods or modes of treatment of physicians of certain diseases are not patentable.”). *But cf.* *Smith & Nephew v. Ethicon*, 54 U.S.P.Q.2d (BNA) 1888, 1889 (D. Ore. 1999) (claiming “a method of attaching tissue to bone by using a resilient suture anchor which is pressed into a hole in the bone”); *Catapano v. Wyeth Ayerst Pharmaceuticals*, 88 F.Supp.2d 27, 28 (E.D.N.Y. 2000) (claiming a method of treating a human patient to effect the remission of AIDS).

<sup>6</sup> *Ex parte Latimer*, 1889 Comm’n Dec. 13 (1889) (holding ineligible for patent protection a claim to “cellular tissues of the *Pinus australis*” tree separated from “the silicious, resinous, and pulpy parts of the pine needles and subdivided into long, pliant filaments adapted to be spun and woven”). *But cf.* *J.E.M. Ag Supply v. Pioneer Hi-Bred International*, 534 U.S. 124 (2001) (holding plants eligible for patent protection).

<sup>7</sup> *Wall v. Leck*, 66 F. 552 (9<sup>th</sup> Cir. 1895) (invalidating patent on a process of fumigating citrus trees in the absence of light).

business methods,<sup>8</sup> mathematical algorithms,<sup>9</sup> and products and phenomena of nature.<sup>10</sup> These exclusions have been viewed skeptically by the Court of Appeals for the Federal Circuit (Federal Circuit) and by its predecessor, the Court of Customs and Patent Appeals (CCPA),<sup>11</sup> and by now most have been repudiated.<sup>12</sup> But thirty years ago the exclusions appeared far more robust. They retained vitality, despite skepticism from the CCPA, because they could claim authority from decisions of the U.S. Supreme Court.<sup>13</sup> This divergence of views between the CCPA on one hand, and the PTO and Supreme Court on the other, set the stage for repeated rejections, appeals, reversals, and further appeals, generating a confusing and inconsistent body of caselaw.<sup>14</sup>

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<sup>8</sup> *Hotel Security Checking Co. v. Lorraine Co.*, 160 F. 467 (2d Cir. 1908) (holding invalid a patent on a “method for cash-registering and account-checking designed to prevent frauds by waiters” while noting that “a system of transacting business disconnected from the means for carrying out the system is not . . . an art.”). *But cf.* *State St. Bank & Trust v. Signature Financial Group*, 149 F.3d 1368 (Fed. Cir. 1998) (rejecting business method exception and stating that basis for *Hotel Security* decision was lack of novelty rather than lack of patent-eligible subject matter).

<sup>9</sup> *Gottschalk v. Benson*, 409 U.S. 63 (1972).

<sup>10</sup> *Funk Bros. Seed v. Kalo Inoculant*, 333 U.S. 127 (1948).

<sup>11</sup> Congress created the Court of Appeals for the Federal Circuit in 1982, consolidating intermediate appellate jurisdiction over patent law matters in a single court that would hear appeals from decisions of the PTO and decisions of the Federal District Courts in patent cases. Federal Courts Improvement Act of 1982, Pub. L. No. 97-164, 96 Stat. 25. An important goal was to bring about greater uniformity and consistency in interpretations of the patent laws.

<sup>12</sup> *E.g.*, *State St. Bank & Trust v. Signature Financial Group*, 149 F.3d 1368 (Fed. Cir. 1998), *cert. denied*, 525 U.S. 1093 (1999); *AT & T Corp. v. Excel Communications, Inc.*, 172 F.3d 1352 (Fed. Cir. 1999); *Pioneer Hi-Bred Int’l v. J.E.M. Ag Supply*, 200 F.3d 1374 (Fed. Cir. 2000), *aff’d sub nom.* *J.E.M. Ag Supply v. Pioneer Hi-Bred Int’l*, 534 U.S. 124, 130 (2001).

<sup>13</sup> *See, e.g.*, *Funk Bros. Seed v. Kalo Inoculant*, 333 U.S. 127 (1948); *Gottschalk v. Benson*, 409 U.S. 63 (1972).

<sup>14</sup> *See, e.g.*, *In re Benson*, 441 F.2d 682 (C.C.P.A. 1971) (reversing PTO rejection of claims to a computer-implemented method of converting numbers expressed in binary coded decimal to pure binary form), *rev’d sub nom.* *Gottschalk v. Benson*, 409 U.S. 63 (1972); *In re Johnston*, 502 F.2d 765 (C.C.P.A. 1974) (reversing PTO rejection of claims to a “machine system for automatic record-keeping of bank checks and deposits”), *rev’d sub nom.*, *Dann v. Johnston*, 425 U.S. 219 (1976); *In re Flook*, 559 F.2d 21 (C.C.P.A. 1977) (reversing PTO rejection of claims to a method of updating alarm limits in a catalytic conversion process through use of a novel mathematical formula), *rev’d sub nom.* *Parker v.*

Supreme Court review has long been something of a wild card in patent law adjudication. Although the U.S. Supreme Court has ultimate appellate jurisdiction over patent cases in the federal courts, patent law consumes relatively little of the Supreme Court's attention, whereas it is a central concern of the PTO and its reviewing court (the Federal Circuit today and the CCPA at the time of the *Chakrabarty* decision). Aggrieved litigants, including the PTO, have often sought Supreme Court review of Federal Circuit (and CCPA) decisions, and occasionally have persuaded the Court to reverse. But the Supreme Court's sporadic interventions in the field have sometimes seemed like rules laid down by a noncustodial parent during weekend visits with the kids—at best, sparingly enforced once everyday life resumes under the supervision of someone whose judgment differs.

A leading voice on the intermediate appellate court for limiting categorical exclusions and for making patent protection available to inventions in all fields was that of Judge Giles Rich, who served first on the CCPA and then on the Federal Circuit for a total of 43 years.<sup>15</sup> As he sometimes noted in his opinions and other writings,<sup>16</sup> Judge Rich played a major role in drafting the Patent Act of 1952 prior to his appointment to the bench in 1956. Judge Rich believed that the 1952 Act had overturned restrictions on the availability of patent protection set forth

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Flook, 437 U.S. 584 (1978); *In re Bergy*, 563 F.2d 1031 (C.C.P.A.1977) (reversing PTO rejection of claims to a biologically pure culture of a microorganism), *vacated and remanded for further consideration in light of Parker v. Flook sub nom. Parker v. Bergy*, 438 U.S. 902 (1978), *on remand*, 596 F.2d 952 (C.C.P.A. 1979) (again reversing rejection of claims), *vacated and remanded with directions to dismiss as moot sub nom. Diamond v. Chakrabarty*, 444 U.S. 1028 (1980); *In re Chakrabarty*, 571 F.2d 40 (C.C.P.A. 1978) (reversing decision of PTO to reject claims to a bacterium that had been genetically engineered to degrade multiple components of crude oil), *cert. dismissed sub nom. Banner v. Chakrabarty*, 439 U.S. 801 (1978), *on rehearing, In re Bergy*, 596 F.2d 952 (C.C.P.A. 1979) (again reversing rejection of claims), *aff'd*, 447 U.S. 303 (1980); *In re Diehr*, 602 F.2d 982 (C.C.P.A. 1979) (reversing PTO rejection of claims to method of curing synthetic rubber which includes use of a mathematical formula and a programmed digital computer), *aff'd sub nom. Diamond v. Diehr*, 450 U.S. 175 (1981).

<sup>15</sup> See Paul R. Michel, *Recollections of Judge Giles S. Rich*, 14 BERKELEY TECH. L.J. 3 (1999), available at <http://www.law.berkeley.edu/journals/btlj/articles/vol14/Michel/html/reader.html>.

<sup>16</sup> *E.g.*, *Paulik v. Rizkalla*, 760 F.2d 1270, 1276 (Fed. Cir. 1985) (Rich, J. concurring) (“I write in order to express some additional thoughts respecting 35 U.S.C. § 102(g) as a member of the group which drafted that section. . . . In my view, considering what I know to have been the intent of [§ 102(g) of the Patent Act], it has been thoroughly misapplied by the board and the dissent here . . .”). See generally Giles S. Rich, *Congressional Intent—Or, Who Wrote the Patent Act of 1952?*, in SOUTHWESTERN LEGAL FOUNDATION, PATENT PROCUREMENT AND EXPLOITATION PROTECTING INTELLECTUAL RIGHTS 61, 78 (1963) (quoting a member of Congress who said that Rich and the other drafters of the statute, “far more than any member of the House or Senate, knew and understood what was intended by the language used.”).

in prior Supreme Court decisions, making the analysis and even the vocabulary of the older cases obsolete and irrelevant.<sup>17</sup>

A leading voice on the Supreme Court for restricting patent eligibility, both before and after passage of the 1952 Act, was that of Justice William O. Douglas, who, before his retirement in 1975, served almost as long on the Supreme Court as Judge Rich served on the intermediate appellate courts.<sup>18</sup> To Justice Douglas, the patent system was a limited exception to an overall preference, on the part of both Congress<sup>19</sup> and the framers of the Constitution,<sup>20</sup> for free competition in the U.S. economy. He believed that patent rights had to be administered parsimoniously to avoid extending monopolies beyond what Congress intended and the Constitution permits.<sup>21</sup> Justice Douglas therefore set high standards for getting a patent and endorsed broad exclusions from patent protection for fundamental building blocks of science and technology such as phenomena of nature<sup>22</sup> and mathematical formulae.<sup>23</sup> Although Justice Douglas was no longer on the Court when it decided *Diamond v. Chakrabarty*, his prior decisions in patent cases remained influential.

Against the backdrop of these competing judicial currents, science and technology moved forward, bringing new technologies before the PTO.

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<sup>17</sup> *E.g.*, *In re Bergy*, 596 F.2d 952, 959 (C.C.P.A. 1979) (noting that pre-1952 cases used the terms “inventions,” “inventive,” and “invent” to convey meanings which the terms no longer have in the revised statute). A notable example of a vocabulary change brought about by the Patent Act of 1952 is the reframing of the Supreme Court’s requirement, drawn from the language of the U.S. Constitution, that a patent could only be issued for an “invention,” into the statutory requirement, set forth in 35 U.S.C. § 103, that in order to be patentable a claimed invention must be “nonobvious.” *Cf.* *Graham v. John Deere*, 383 U.S. 1 (1966) (noting that the limitation of patent protection to “inventions” is required by the Constitution, that the Court interprets the statutory standard of “nonobviousness” to be consistent with the Constitutional limitation, and that if Congress were in fact to diminish the standard for protection below that required by the Constitution, the Court would be compelled to hold the statute invalid).

<sup>18</sup> Justice Douglas was appointed to the Supreme Court in 1939 and retired in 1975, for a total term of 36 1/2 years. Oyez U.S. Supreme Court Multimedia, *William O. Douglas*, [http://www.oyez.org/oyez/resource/legal\\_entity/79/](http://www.oyez.org/oyez/resource/legal_entity/79/) (last visited Jul. 25, 2005).

<sup>19</sup> *Kewanee Oil v. Bicron*, 416 U.S. 470, 495 (1974) (Douglas, J., dissenting) (“Congress in the patent laws decided that where no patent existed, free competition should prevail. . . .”).

<sup>20</sup> *A & P Tea v. Supermarket Corp.*, 340 U.S. 147, 154 (1950) (Douglas, J., concurring) (“The Congress does not have free rein . . . to decide that patents should be easily or freely given. . . . The Framers plainly did not want those monopolies freely granted.”).

<sup>21</sup> *Id.*

<sup>22</sup> *Funk Bros. Seed v. Kalo Inoculant*, 333 U.S. 127 (1948).

<sup>23</sup> *Gottschalk v. Benson*, 409 U.S. 63 (1972).

### Chakrabarty's Invention

Ananda Chakrabarty is a Distinguished Professor of Microbiology and Immunology at the University of Illinois who has accumulated a long list of scientific publications over a career spanning four decades.<sup>24</sup> But in legal circles, he is better known as the patent applicant who litigated the issue of the patentability of living organisms in the landmark Supreme Court case of *Diamond v. Chakrabarty*.<sup>25</sup>

After completing his Ph.D. at the University of Calcutta in 1965, Chakrabarty went to the University of Illinois at Urbana as a postdoctoral associate, where he studied the ability of *Pseudomonas* bacteria to utilize a wide variety of organic compounds as nutrition. In the course of this work, he discovered that the genes that allowed the bacteria to digest compounds such as camphor and octane did not reside on the bacterial chromosome, but rather on separate DNA elements called plasmids that are more readily transmissible from one bacterium to another. Chakrabarty's research demonstrated the potential of *Pseudomonas* bacteria to transfer between organisms plasmids containing the genes that permit assimilation of these compounds, thereby enhancing their nutritional versatility.<sup>26</sup>

In 1971 Chakrabarty left the University of Illinois for a position in the Research and Development Center of General Electric, where he was assigned to work on the nutritionally frugal (if unappetizing) problem of converting cow manure into cattle feed.<sup>27</sup> But he retained an interest in basic research, and soon found a persuasive commercial justification for continuing his prior research on *Pseudomonas*. In the early 1970s, in some parts of the world, oil was cheap, but protein sources were

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<sup>24</sup> A list of Chakrabarty's scientific publications is posted at <http://www.uic.edu/depts/mcmi/faculty/chakrabarty.html> (last visited Oct. 4, 2004).

<sup>25</sup> 447 U.S. 303 (1980). This decision was the focus of extensive law review commentary. See, e.g., Peter B. Maggs, *New Life for Patents: Chakrabarty and Rohm & Haas Co.*, 1980 SUP. CT. REV. 57 (1980); Note, *The Patentability of Living Matter: Hey Waiter, What's Chakrabarty's Pseudomonas Bacterium Doing Back in the Supreme Court's Soup?*, 37 WASH. & LEE L. REV. 183 (1980); Note, *Live, Human-made Bacteria As Patentable Subject Matter Under 35 U.S.C. § 101: Diamond v. Chakrabarty*, 1980 BYU L. REV. 705 (1980); Note, *Diamond v. Chakrabarty: Living Things as Statutory Subject Matter*, 1 N. ILL. U. L. REV. 119 (1980); Note, *Patentability of Living Microorganisms: Diamond v. Chakrabarty*, 94 HARV L. REV. 261 (1980); Note, *Diamond v. Chakrabarty: Oil Eaters: Alive and Patentable*, 8 PEPP L. REV. 747 (1981); Note, *Building a Better Bacterium: Genetic Engineering and the Patent Law After Diamond v. Chakrabarty*, 81 COLUM. L. REV. 159 (1981).

<sup>26</sup> Ananda M. Chakrabarty, *Patenting of Life-Forms From a Concept to Reality*, in D. MAGNUS ET AL., *WHO OWNS LIFE?* (2002). The definitive historical account of the Chakrabarty case is Daniel J. Kevles, *Ananda Chakrabarty wins a patent: Biotechnology, law, and society, 1972-1980*, 25 HIST STUD. IN THE PHYSICAL AND BIOLOGICAL SCIENCES 111 (1994).

<sup>27</sup> Kevles, *supra* note 26, at 114.



expensive. These relative values made it commercially attractive to develop a process for converting crude oil to bacterial biomass (which would ultimately provide nutrition higher up in the food chain).<sup>28</sup> It occurred to Chakrabarty that *Pseudomonas* bacteria could be put to use in this bioconversion task, since he knew they could derive nutrition from various components of crude oil. But crude oil is a mixture of many different hydrocarbons, of which known *Pseudomonas* strains could only degrade a limited number. A mixed culture of strains could potentially digest more components, but some strains inevitably dominated others in mixed cultures, limiting the extent of degradation (and therefore limiting the generation of biomass). Knowing from his prior work that the genes for degrading the separate components were borne on plasmids that could be transferred from one bacterium to another, Chakrabarty hit upon the idea of constructing a single *Pseudomonas* strain with multiple plasmids. He worked on the problem after-hours and on weekends, and eventually succeeded.<sup>29</sup> While his research proceeded, the price of crude oil rose substantially in world markets, calling into question the value of the strain as a means of converting petroleum to biomass. But his colleagues at GE decided that an oil-eating bacterium might nonetheless be useful for another purpose—cleaning up oil spills—and on June 7, 1972, GE filed a patent application on Chakrabarty's invention.<sup>30</sup>

### The PTO's Response

Patents on technologies involving the use of microorganisms were by this point familiar subject matter for the patent system. The pharmaceutical industry had been securing patents on methods of producing antibiotics from microbial strains for decades,<sup>31</sup> and patents on microbial processes for waste treatment were older still.<sup>32</sup> What made Chakrabarty's application unusual was that he claimed not only methods of using his bacterial strains, but also the bacteria themselves.

The patent examiner allowed Chakrabarty's process claims, but rejected the product claims to the bacteria on two grounds: (1) that the claimed microorganisms are "products of nature"; and (2) that as "live organisms" they are not eligible for patent protection.<sup>33</sup> Chakrabarty

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<sup>28</sup> Chakrabarty, *supra* note 26, at 18.

<sup>29</sup> *Id.* at 19.

<sup>30</sup> *Id.* at 19–20.

<sup>31</sup> *E.g.*, *In re Mancy*, 499 F.2d 1289 (C.C.P.A. 1974) (upholding patent claims to process of making antibiotic by cultivating strain of bacteria).

<sup>32</sup> *E.g.*, *City of Milwaukee v. Activated Sludge*, 69 F.2d 577 (7th Cir. 1934) (patent on method of treating raw sewage).

<sup>33</sup> *In re Chakrabarty*, 571 F.2d 40, 42 (C.C.P.A. 1978).

appealed the rejection to the PTO Board of Appeals (the Board). The Board set aside the examiner's holding that the bacteria were products of nature, agreeing with Chakrabarty that his multi-plasmid *Pseudomonas* bacteria were not naturally occurring, but nonetheless affirmed the rejection on the ground that living organisms may not be patented.<sup>34</sup>

Meanwhile, in *Ex parte Bergy*,<sup>35</sup> a different Board panel applied a similar analysis to an appeal from a rejection of a claim to a "biologically pure culture" of an antibiotic-producing microorganism. Bergy's organism had not been genetically altered, and thus might have been more readily characterized as a "product of nature" than Chakrabarty's multi-plasmid bacterium. (Indeed, the sole basis for the examiner's rejection of Bergy's claim was that it constituted an unpatentable product of nature.)<sup>36</sup> But the Board declined to consider whether the biologically pure culture was a product of nature, and instead affirmed the rejection on the different ground that it was living, and thus was not a patentable "manufacture" or "composition of matter" within the meaning of § 101 of the Patent Act.<sup>37</sup>

In both cases, the Board thus set aside the "products of nature" ground for rejections and focused instead on the fact that the claims were drawn to living subject matter. In retrospect, this choice seems both puzzling and fateful. Although patent applications on living organisms had been rejected in the past,<sup>38</sup> there was no precedent explicitly stating that living things are *ipso facto* ineligible for patent protection. Instead, the stated ground for exclusion had been that they were unpatentable products of nature. Under the circumstances, one might expect that the PTO would retain on appeal the tried-and-true ground for rejection rather than resting solely on an argument that the courts had never considered.

To be sure, the products of nature argument was problematic in the facts of both *Chakrabarty* and *Bergy*. A series of cases had previously upheld patents on purified versions of products that exist in nature only in an impure state, reasoning that the purified products were the result of human intervention, and that in a purified state they were suitable for purposes that the impure versions could not serve.<sup>39</sup> Similar arguments

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<sup>34</sup> 571 F.2d at 42.

<sup>35</sup> 197 U.S.P.Q. (BNA) 78 (U.S. P.T.O. Bd. App. & Interf., 1976), *rev'd sub nom. In re Bergy*, 563 F.2d 1031 (C.C.P.A. 1977).

<sup>36</sup> *In re Bergy*, 563 F.2d at 1032-33.

<sup>37</sup> 197 U.S.P.Q. (BNA) at 79-80; 563 F.2d at 1033.

<sup>38</sup> *E.g.*, *Ex parte Latimer*, 1889 Comm'n Dec. 13 (1889).

<sup>39</sup> *E.g.*, *Parke-Davis & Co. v. H.K. Mulford & Co.*, 189 F. 95 (S.D.N.Y. 1911) (purified adrenaline); *Kuehmsted v. Farbenfabriken*, 179 F. 701 (7th Cir. 1910), *cert. denied*, 220

could be made for the organisms claimed by both Chakrabarty and Bergy. But none of the “purified substances” cases had been affirmed by the Supreme Court.

Indeed, the Supreme Court had seemed to endorse a more expansive exclusion in its 1948 decision in *Funk Brothers Seed Company v. Kalo Inoculant*,<sup>40</sup> a case with notable similarities to *Chakrabarty*. The patent at issue in that case claimed a mixed culture of naturally occurring strains of bacteria of the genus *Rhizobium*, useful as an inoculant to permit plants to fix nitrogen from the environment. In the past, different species of *Rhizobium* had been used to inoculate the roots of different plants, but when multiple strains were combined, they had inhibited each other’s effectiveness. The inventor, Bond, identified strains that did not have this mutually inhibitive effect and combined them in a single product that could be used to inoculate multiple crops. The PTO issued the patent and, in a subsequent infringement action, the Court of Appeals upheld the validity of Bond’s claim to the mixed culture, characterizing it as a new composition of matter that contributed utility and economy to the manufacture and distribution of commercial inoculants. The Supreme Court reversed. In an opinion by Justice Douglas, the Court elaborated upon the exclusion of the work of nature from patent protection:

Bond does not create a state of inhibition or of non-inhibition in the bacteria. Their qualities are the work of nature. Those qualities are of course not patentable. For patents cannot issue for the discovery of the phenomena of nature. The qualities of these bacteria, like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men. They are manifestations of laws of nature, free to all men and reserved exclusively to none. He who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes. If there is to be invention from such a discovery, it must come from the application of the law of nature to a new and useful end.<sup>41</sup>

Justice Douglas conceded that Bond had indeed applied his discovery of the noninhibitive qualities of the bacterial strains to a new and useful end by combining them into a new product—the mixed culture of his claim.<sup>42</sup> He nonetheless concluded that the product was not patentable, in language that sometimes suggested a categorical exclusion and some-

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U.S. 622 (1911) (purified prostaglandins); *Merck & Co. v. Olin Mathieson Corp.*, 253 F.2d 156 (4th Cir. 1958) (purified vitamin B12).

<sup>40</sup> 333 U.S. 127 (1948).

<sup>41</sup> *Id.* at 130.

<sup>42</sup> *Id.* at 131–32.

times suggested a failure to meet the patent law standard for “invention”:

But we think that that aggregation of species fell short of invention within the meaning of the patent statutes. Discovery of the fact that certain strains of each species of these bacteria can be mixed without harmful effect to the properties of either is a discovery of their qualities of non-inhibition. It is no more than the discovery of some of the handiwork of nature and hence is not patentable. . . . [H]owever ingenious the discovery of the natural principle may have been, the application of it is hardly more than an advance in the packaging of the inoculants. . . . The combination of species produces no new bacteria, no change in the six species of bacteria, and no enlargement of the range of their utility. Each species has the same effect it always had. The bacteria perform in their natural way. Their use in combination does not improve in any way their natural functioning. They serve the ends nature originally provided and act quite independently of any effort of the patentee.<sup>43</sup>

One could, by analogy, have argued that Chakrabarty had also discovered some of the handiwork of nature—naturally occurring plasmids that could be transferred from one microbial host to another, each permitting its host to degrade a different component of crude oil—and combined them in a single host organism. As Chakrabarty himself explained in a 1980 interview with *People*, “I simply shuffled genes, changing bacteria that already existed.”<sup>44</sup> In Chakrabarty’s combination, as in Bond’s, each of the subunits (Chakrabarty’s plasmids, Bond’s species) continued to perform in its natural way. If Chakrabarty’s aggregation of multiple selected plasmids in a single organism required more ingenuity than Bond’s aggregation of selected species in a mixed culture inoculant, this distinction would seem to be a matter of nonobviousness, or “invention” in the vernacular of pre-1952 Act decisions, rather than a matter of patent eligibility.

The distinction between the threshold question of patent eligibility and the more fine-grained question of patent-worthiness was easy to miss in the pre-1952 cases, when the single term “invention” might be used to describe what was lacking in both situations.<sup>45</sup> The 1952 Act

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<sup>43</sup> *Id.* at 131.

<sup>44</sup> *PEOPLE*, July 14, 1980, at 38 (as cited in Kevles, *supra* note 26, at 116).

<sup>45</sup> *Compare* *Mackay Radio & Telegraph Co. v. Radio Corp. of America*, 306 U.S. 86, at 96 n.4 (1939) (“While a scientific truth, or the mathematical expression of it, is not patentable *invention*, a novel and useful structure created with the aid of knowledge of scientific truth may be.” (emphasis added)) *with* *Great Atlantic & Pacific Tea Co. v. Supermarket Equipment Corp.*, 340 U.S. 147, 149 (1950) (“Courts should scrutinize

codified the requirement of “invention” in the latter sense and gave it a new name, “nonobviousness,”<sup>46</sup> but *Funk v. Kalo* was decided before that time and explained in language that left a lingering ambiguity about whether Bond’s invention was categorically ineligible for patent protection or was merely unworthy of patent protection because it was trivial. This ambiguity may have made *Funk v. Kalo* questionable as authority for rejecting the claims of Chakrabarty and Bergy.

But *Funk v. Kalo* was not the last word from the Supreme Court on this subject. Even after passage of the 1952 Act, in the years leading up to its decision in *Diamond v. Chakrabarty* the Supreme Court had relied on *Funk v. Kalo* in two more cases, each involving rejections of claims to computer-implemented inventions.<sup>47</sup> Although the precedential value of a case about a mixed culture of bacteria for resolving cases about computer-implemented inventions might not be self-evident, Justice Douglas, writing for the Court, not only cited *Funk v. Kalo* with approval but seemed to rely upon it:

Phenomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work. As we stated in *Funk Bros. Seed Co. v. Kalo Co.*, “He who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes. If there is to be invention from such a discovery, it must come from the application of the law of nature to a new and useful end.” We dealt there with a “product” claim, while the present case deals with a “process” claim. But we think the same principle applies.<sup>48</sup>

Categorical exclusions from patent eligibility for “products of nature” thus retained considerable vitality in the Supreme Court in the 1970s, making it all the more puzzling that the PTO would set aside this ground for rejecting the Chakrabarty and Bergy claims while resting

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combination patent claims with a care proportioned to the difficulty and improbability of finding *invention* in an assembly of old elements.” (emphasis added).

<sup>46</sup> 35 U.S.C. § 103; *Graham v. John Deere*, 383 U.S. 1 (1966).

<sup>47</sup> In the first of these cases, *Gottschalk v. Benson*, 409 U.S. 63 (1972), a unanimous Court overturned the CCPA and reinstated the PTO’s rejection of a claim to a method of converting binary-coded decimal numerals into pure binary numerals. The Court again invoked the “products of nature” cases in its 6–3 decision in *Parker v. Flook* to overturn the C.C.P.A. and reinstate the PTO’s rejection of a claim to a computer-implemented method for updating an alarm limit in the startup of a catalytic conversion plant. 437 U.S. 584 (1978). This 1978 decision had not yet come down when the PTO Board decided the *Chakrabarty* and *Bergy* cases. See *infra* notes 72 to 79 and accompanying text. For a fuller discussion of *Gottschalk v. Benson* and *Parker v. Flook*, see Maureen A. O’Rourke, *The Story of Diamond v. Diehr: Toward Patenting Software*, elsewhere in this Volume.

<sup>48</sup> 409 U.S. at 67–68 (citation omitted).

solely on an unprecedented categorical exclusion for living things. It is generally easier to persuade courts to adjust the boundaries of existing legal categories to accommodate new facts than it is to persuade them to create new categories.

Lacking explicit precedent for the principle that living things may not be patented, the PTO was left to make a complex, and ultimately unpersuasive, argument for an inference about Congressional intent (or assumptions) concerning the patentability of living things from the fact that Congress had passed special legislation to provide intellectual property protection for plants. The argument went as follows: Congress twice acted to provide intellectual property rights in plants: first, in the Plant Patent Act of 1930, which conferred patent rights in asexually reproduced plants;<sup>49</sup> and second, in the Plant Variety Protection Act of 1970, which conferred more limited protection under the auspices of the Department of Agriculture for sexually reproduced varieties.<sup>50</sup> Since Congress went to the trouble of passing special legislation to provide protection for plants, Congress must have believed that, absent such legislation, plants would not be eligible for ordinary utility patent protection under the general patent statute. Congress must therefore have believed that plants did not fit within the existing patentable subject matter categories of "manufacture" or "composition of matter." The reason Congress thought that plants were excluded from those statutory categories must have been that plants are living, and therefore Congress must have believed that the statutory categories of patentable subject matter excluded not only plants, but also all other living things. From legislation that made it easier to get protection for plants, the PTO thus drew an inference that Congress intended as a general rule to exclude all living things from patent eligibility.

To recite this syllogism is to draw a roadmap for its rebuttal. The relevant statutory language was, at the time, almost 200 years old, and the actions of later Congresses is a questionable source for understanding the meaning of language used by an earlier Congress. Quite apart from this difficulty, it is easy to come up with competing explanations that are equally compelling. Perhaps, rather than believing that plants were categorically excluded from the patent system on subject matter grounds, Congress believed that plants could not satisfy the usual standards for getting a patent (such as "invention"/nonobviousness and written description) and wished to provide a source of protection that avoided these obstacles. (Indeed, both the Plant Patent Act and the Plant Variety Protection Act provided relief from some of the more

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<sup>49</sup> 46 Stat. 376, codified as amended at 35 U.S.C. §§ 161 et seq.

<sup>50</sup> 84 Stat. 1547, codified as amended at 7 U.S.C. §§ 2402 et seq.

stringent requirements of patent law for plants.)<sup>51</sup> Perhaps Congress believed that plants were ineligible for patent protection not because they were living, but because they were products of nature. Perhaps Congress focused narrowly on the problems of plant breeders because that was the issue before them, and gave no thought to the patenting of other living things.

However narrowly Congress may have focused its attention in 1930 and in 1970, it is hardly possible that the PTO and the courts were oblivious to public controversy over biotechnology as they contemplated the issues before them in *Chakrabarty* and *Bergy*. The invention in the early 1970s of recombinant DNA techniques, which permitted scientists to create new organisms by splicing together genes from different species, had provoked profound anxiety among scientists as well as the general public.<sup>52</sup> While most scientists soon concluded that initial worries about the hazards of gene-splicing had been overstated,<sup>53</sup> popular interest and anxiety continued, taking on a new dimension with the advent of commercial biotechnology in the latter half of the 1970s.<sup>54</sup> Although neither *Chakrabarty* nor *Bergy* had used recombinant DNA technology in making their inventions, it was surely apparent to those considering their cases that their decisions would have important implications for future inventions in this controversial new field.<sup>55</sup>

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<sup>51</sup> See 35 U.S.C. § 162 (“No plant patent shall be declared invalid for noncompliance with section 112 of this title [regarding description and disclosure] if the description is as complete as is reasonably possible.”). The Plant Variety Protection Act has no counterpart to the nonobviousness requirement and has disclosure requirements that are easier to meet than those for an ordinary utility patent. For a comparison of the two schemes, see Mark D. Janis & Jay P. Kesan, *U.S. Plant Variety Protection: Sound and Fury . . . ?*, 39 HOUS. L. REV. 727, 745–78 (2002).

<sup>52</sup> Concerns within the scientific community led to a historic conference of molecular biologists at the Asilomar conference center in Pacific Grove, California to discuss the hazards associated with recombinant DNA research in early 1975. Much has been written about these events. A useful synthesis may be found in Judith P. Swazey, James R. Sorenson, & Cynthia B. Wong, *Risks and Benefits, Rights and Responsibilities: A History of the Recombinant DNA Research Controversy*, 51 SO. CAL. L. REV. 1019–78 (1978). For an interesting retrospective on the controversy within the scientific community from the perspective of the NIH Director at the time, see Donald S. Fredrickson, *Asilomar and Recombinant DNA: The End of the Beginning*, in Institute of Medicine, *BIOMEDICAL POLITICS* (1991). For a more critical perspective, see Sheldon Krimsky, *GENETIC ALCHEMY THE SOCIAL HISTORY OF THE RECOMBINANT DNA CONTROVERSY* (1982).

<sup>53</sup> Kevles, *supra* note 26, at 121.

<sup>54</sup> See MARTIN KENNEY, *BIOTECHNOLOGY. THE UNIVERSITY-INDUSTRIAL COMPLEX* 90–106, 132–75 (1986); DAVID DICKSON, *THE NEW POLITICS OF SCIENCE* 56–106 (1984).

<sup>55</sup> *Cf.* Kevles, *supra* note 26, at 121 (suggesting that “considerations of political economy of biotechnology” did not figure in the PTO’s analysis until after its decision had been reversed by the C.C.P.A., when it had to decide whether to appeal to the Supreme

Perhaps awareness of contemporary social discourse best accounts for the PTO's focus on "living things" rather than "products of nature" as the basis for rejecting the claims. In the rhetoric of the "products of nature" cases, it was nature that had done the heavy lifting, creating products and phenomena with awesome capabilities. The value-added of human inventors was relatively trivial, consisting primarily of figuring out what nature had done and then making minor adaptations without really changing much. In the anxious rhetoric surrounding genetic engineering in the 1970s, the relationship between nature and human inventors was pictured quite differently. Human interventions in this setting did not seem trivial, but profound and unsettling. Rather than merely copying from nature, humans seemed to be altering nature's plans in unprecedented (and, to some, alarming) ways. Neither proponents nor adversaries of the new technology saw it as the work of nature. The concerns and intuitions that had persuaded previous courts to leave natural products and natural phenomena as part of an unpatented "storehouse of knowledge . . . free to all men and reserved exclusively to none" may thus have seemed inapposite in that particular historical moment.<sup>56</sup>

Even if the products of nature doctrine could serve to exclude the relatively "low-tech" inventions of Chakrabarty and Bergy, it was unlikely to stretch far enough to exclude the results of "high-tech" genetic engineering from the patent system. The essence of public anxiety about genetic engineering was not that it was natural, but rather that it was *unnatural*, that it amounted to audacious human tampering with life. An argument for excluding living things from patent protection, although lacking explicit support in precedent, may have resonated more closely with this sentiment than the time-honored argument for excluding products of nature.

### The CCPA Reverses

Chakrabarty and Bergy each appealed the rejections of their claims to the CCPA, which reversed in each case by a vote of 3–2.<sup>57</sup> Both

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Court). But even prior to that time, as the PTO was deciding the *Chakrabarty* and *Bergy* appeals in the first instance, PTO personnel were surely aware of extensive coverage of controversy over recombinant DNA research in both the scientific press, e.g., Davis, *Genetic Engineering: How Great Is the Danger?*, 186 *SCIENCE* 309 (1974); Erwin Chargaff, *A Slap at the Bishops of Asilomar*, 190 *SCIENCE* 135 (1975), and the popular press, e.g., Horace F. Judson, *Fearful of Science: after Copernicus, after Darwin, after Freud comes molecular biology. Is nothing sacred?*, 250 *HARPER'S* 1498 (1975); Bennett & Guerin, *Science That Frightens Scientists*, *ATLANTIC MONTHLY*, Feb. 1977, at 49.

<sup>56</sup> Concerns about patents on natural phenomena impeding future scientific work resurfaced much later in controversies over the patenting of DNA sequences as the Human Genome Project got under way in the 1990s. See Rebecca S. Eisenberg, *Why the Gene Patenting Controversy Persists*, 77 *ACADEMIC MEDICINE* 1381 (2002).

<sup>57</sup> *In re Bergy*, 563 F.2d 1031 (C.C.P.A. 1977); *In re Chakrabarty*, 571 F.2d 40 (C.C.P.A. 1978).



majority opinions were authored by Judge Rich, who took care to isolate the issue for decision as narrowly as possible. He began each opinion by stating that the PTO had not questioned that the inventions satisfied the statutory criteria for patentability apart from the issue of statutory subject matter.<sup>58</sup> He then reviewed the proceedings in the PTO, noting in each case that, although the examiners had rejected the claimed inventions as “products of nature,” the Board had affirmed instead on the different ground that statutory subject matter does not extend to “living subject matter.”<sup>59</sup> Having thus pared each case down to the single issue of whether living subject matter may be patented, he had little trouble concluding that it could be. The *Bergy* case, although filed after Chakrabarty’s, was the first to reach the CCPA. The court therefore addressed the issue at greater length in *Bergy* than in *Chakrabarty*, concluding in *Chakrabarty* that the two cases raised exactly the same issue and therefore the former decision controlled.

Judge Rich observed in *Bergy* that, although the PTO had only addressed the single issue of whether living organisms are eligible for patent protection, *Bergy* had also argued on appeal “the product of nature question sidetracked by the Board.”<sup>60</sup> Characterizing as “incontrovertible” *Bergy*’s evidence that the biologically pure culture does not occur in nature, Judge Rich surmised that “the board went in search of another reason to support the rejection because it realized the examiner’s position was untenable,” and concluded: “The biologically pure culture of claim 5 clearly does not exist in, is not found in, and is not a product of ‘nature.’”<sup>61</sup>

Turning to the PTO’s argument that living organisms are unpatentable, he began with the “clarifying observation” that “we are not deciding whether living things in general, or, at most, whether any living things other than microorganisms, are within § 101. These questions must be decided on a case-by-case basis. . . .” He then considered a series of decisions cited by the PTO in which the claims at issue had been drawn to processes of using microorganisms, and the courts had suggest-

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<sup>58</sup> *In re Bergy*, 563 F.2d at 1032 (“No references have been cited against claim 5 because the novelty and unobviousness of the biologically pure culture claimed are not questioned. Neither has utility been questioned.”); *In re Chakrabarty*, 571 F.2d at 42 (“The PTO . . . has not questioned that appellant has invented and adequately disclosed strains of bacteria . . . which are new, useful, and unobvious.”).

<sup>59</sup> *In re Bergy*, 563 F.2d at 1033; *In re Chakrabarty*, 571 F.2d at 42.

<sup>60</sup> 563 F.2d at 1035.

<sup>61</sup> *Id.*

ed in *dicta* that the microorganisms themselves would not have been patentable.<sup>62</sup> Turning the PTO's analysis of these cases on its head, Judge Rich observed that "processes, one of the categories of patentable subject matter specified in § 101, are uniformly and consistently considered to be statutory subject matter notwithstanding the employment therein of living organisms and their life processes."<sup>63</sup> It would be "illogical," he concluded, to insist that "the existence of life in a manufacture or composition of matter" renders such products unpatentable, while "the functioning of a living organism and the utilization of its life functions in processes does not affect their status under § 101."<sup>64</sup> To Judge Rich, Bergy's culture was "an industrial product used in an industrial process—a useful or technological art if there ever was one."<sup>65</sup> Characterizing the organisms and their uses as "much more akin to inanimate chemical compositions such as reactants, reagents, and catalysts than they are to horses and honeybees or raspberries and roses," he concluded that the PTO's fears that their patenting would make "all new, useful, and unobvious species of plants, animals, and insects created by man patentable" was "far-fetched."<sup>66</sup> Having thus resolved that microorganisms are not categorically excluded from patent eligibility, he concluded that the rejection in *Chakrabarty* must also be reversed when that case came before him five months later.<sup>67</sup>

By this point the advent of commercial biotechnology had raised the stakes of the controversy over patentability of microorganisms. The day after the CCPA's decision in *Chakrabarty*, a front-page story in *The Washington Post* reported that the decision "represents a potential gold mine for corporations involved in genetic engineering research."<sup>68</sup> Among scientists, anxiety about the hazards of genetic engineering had begun to subside, leading the National Institutes of Health (NIH) to relax previously imposed safety restrictions on use of the technology by its grantees.<sup>69</sup> But controversy continued among the general public, with

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<sup>62</sup> *Id.* at 1035–37.

<sup>63</sup> *Id.* at 1037.

<sup>64</sup> *Id.*

<sup>65</sup> *Id.* at 1038.

<sup>66</sup> *Id.* at 1038–39. The two dissenters characterized Judge Rich's distinction between microorganisms and other living things as "purely gratuitous and clearly erroneous," noting that the majority had failed to "advance any rationale for distinguishing between different types of living things. . . ."

<sup>67</sup> *In re Chakrabarty*, 571 F.2d 40, 43 (C.C.P.A. 1978).

<sup>68</sup> Austin Scott, *Court Rules GE Can Patent Life Created in Lab*, WASH. POST, Mar. 3, 1978, at A1. See also, *Oil-Eating Bacterium Can Be Patented by G.E.*, *Court Rules in 3-2 Vote*, N.Y. TIMES, Mar. 3, 1978, at A26.

<sup>69</sup> 43 F.R. 60080 (Dec. 22, 1978).

some local governments considering their own restrictions on biotechnology research as federally-imposed restrictions were relaxed.<sup>70</sup>

While the government pondered its options, the PTO was aware of the precarious force of Judge Rich's decisions in the face of continuing public controversy.<sup>71</sup> At the time, intermediate appellate jurisdiction over patent matters was divided between the CCPA, which heard appeals from decisions of the PTO, and the regional circuit courts of appeal, which heard appeals from decisions of the federal district courts in patent infringement cases. These other courts might not share Judge Rich's picture of industrial biotechnology as merely an efficient way to do chemistry, and might declare patents on life forms invalid when they came before them for enforcement. The PTO ultimately urged the Solicitor General to appeal the issue to the U.S. Supreme Court, figuring that the issue would eventually be resolved by Congress.<sup>72</sup>

### Remand and Reconsideration

While the government's petitions for review in *Bergy* and *Chakrabarty* were pending, the Supreme Court reversed the CCPA in another case involving patent eligibility, *Parker v. Flook*.<sup>73</sup> The invention in that case was a computer-implemented method for updating alarm limits during catalytic conversion processes through use of a novel mathematical formula. Justice Stevens's opinion for the majority took a strikingly different approach to the issue of patent eligibility than that expressed by Judge Rich. He began by noting that the Court's decision six years earlier in *Gottschalk v. Benson*<sup>74</sup> was inconsistent with a literal interpretation of § 101 of the Patent Act, notwithstanding the apparently unqualified language of the statute:

The plain language of 101 does not answer the question. It is true, as respondent argues, that his method is a "process" in the ordinary sense of the work. But that was also true of the algorithm . . . that was involved in *Gottschalk v. Benson*. The holding that the discovery of that method could not be patented as a "process" forecloses a purely literal reading of 101.<sup>75</sup>

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<sup>70</sup> See Donald S. Fredrickson, *The Recombinant DNA Controversy: A Memoir: Science, Politics & the Public Interest 1974–1981* (2001), available at National Library of Medicine, <http://profiles.nlm.nih.gov/FF/Views/Exhibit/documents/rdna>.

<sup>71</sup> Kevles, *supra* note 26, at 122–123.

<sup>72</sup> *Id.*

<sup>73</sup> 437 U.S. 584 (1978).

<sup>74</sup> 409 U.S. 63 (1972).

<sup>75</sup> *Parker v. Flook*, 437 U.S. at 589–90.

Echoing Justice Douglas's analogy between mathematical algorithms and laws of nature in *Gottschalk v. Benson*, the majority concluded that the Court's earlier decision in *Funk v. Kalo* indicated the proper analysis:

Whether the algorithm was in fact known or unknown at the time of the claimed invention, as one of the "basic tools of scientific and technological work," it is treated as though it were a familiar part of the prior art. . . .<sup>76</sup>

The Court rejected the argument that this approach confuses the determination of patent eligibility under § 101 with the determinations of novelty and "inventiveness" under §§ 102 and 103. In language reminiscent of Justice Douglas's opinion in *Funk v. Kalo*, Justice Stevens elaborated:

The rule that the discovery of a law of nature cannot be patented rests, not on the notion that natural phenomena are not processes, but rather on the more fundamental understanding that they are not the kind of "discoveries" that the statute was enacted to protect. The obligation to determine what type of discovery is sought to be patented must precede the determination of whether that discovery is, in fact, new or obvious. . . . Respondent's process is unpatentable under 101, not because it contains a mathematical algorithm as one component, but because once that algorithm is assumed to be within the prior art, the application, considered as a whole, contains no patentable invention.<sup>77</sup>

Yet there were signs that the Supreme Court was softening in its approach to patent eligibility. The Court acknowledged that its reasoning was "derived from opinions written before the modern business of developing programs for computers was conceived,"<sup>78</sup> and that its decision should not be interpreted "as reflecting a judgment that patent protection of certain novel and useful computer programs will not promote the progress of science and the useful arts, or that such protection is undesirable as a matter of policy."<sup>79</sup> Rather, the Court saw the issue before it as raising "difficult questions of policy" that could better be answered by Congress, and concluded that "we must proceed cautiously when we are asked to extend patent rights into areas wholly unforeseen by Congress."<sup>80</sup>

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<sup>76</sup> *Id.* at 591–92.

<sup>77</sup> *Id.* at 593–94.

<sup>78</sup> *Id.* at 595.

<sup>79</sup> *Id.*

<sup>80</sup> *Id.* at 596, citing *Deepsouth Packing Co. v. Laitram Corp.*, 406 U.S. 518, 531 (1972). Perhaps the most conspicuous harbinger of the Court's imminent liberalization of its

A few days later, the Supreme Court vacated the decision of the CCPA in *Bergy* and remanded for reconsideration in light of *Parker v. Flook*.<sup>81</sup> The CCPA granted the PTO's petition to vacate its own decision in *Chakrabarty* and set the two cases for hearing together, asking the parties to file supplementary briefs on the effect, "if any," of *Parker v. Flook* on its prior decisions.<sup>82</sup>

Judge Rich again wrote for the majority on reconsideration, again reversing the rejections in both cases. He was conspicuously unimpressed by the *Flook* decision and visibly irritated at the government for having taken the cases up to the Supreme Court. He began with a back-to-basics review of the anatomy of the patent statute, purportedly for the benefit of the Supreme Court, which he felt had exposed some confusion about the statute in its *Flook* opinion:

The reason for our consideration of the statutory scheme . . . is that . . . we find in *Flook* an unfortunate and apparently unconscious, though clear, commingling of distinct statutory provisions which are conceptually unrelated, namely, those pertaining to the categories of inventions in § 101 which may be patentable and to the conditions for patentability demanded by the statute for inventions within the statutory categories, particularly the nonobviousness condition of § 103. . . . The problem of accurate unambiguous expression is exacerbated by the fact that prior to the Patent Act of 1952 the words "invention," "inventive," and "invent" had distinct legal implications related to the concept of patentability which they have not had for the past quarter century. . . . Statements in the older cases must be handled with care lest the terms used in their reasoning clash with the reformed terminology of the present statute; lack of meticulous care may lead to distorted legal conclusions.<sup>83</sup>

He offered an analogy to three doors that a patent applicant must open and pass through in order to get a patent, corresponding to §§ 101, 102,

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interpretation of § 101 was the fact that three justices dissented, taking the position that the majority was confusing the issue of subject-matter patentability under § 101 with the criteria of novelty and inventiveness under §§ 102 and 103. *Parker v. Flook*, 437 U.S. at 598, 600 (Stewart, J. dissenting, joined by Burger, C.J., and Rehnquist, J.).

<sup>81</sup> *Parker v. Bergy*, 438 U.S. 902 (1978).

<sup>82</sup> *In re Bergy*, 596 F.2d 952, 956-58 (C.C.P.A. 1979).

<sup>83</sup> *Id.* at 599. The unmistakable condescension toward the Supreme Court in Judge Rich's opinion led amicus University of California to distance itself from the opinion of the CCPA in its Supreme Court brief, even as it asked the Supreme Court to affirm the decision, noting that the CCPA "tends toward legal error and has long waged war against this Court's venerable and unvaried interpretations of the patent laws." Brief Amicus Curiae of the University of California at 24 (filed Jan. 28, 1980) (Westlaw Supreme Court Briefs file).

and 103 of the Patent Act. To get through the first door, the invention need not satisfy any “qualitative conditions,” so long as it fits within the “broad and general” categories of “any . . . process, machine, manufacture, or composition of matter, or any . . . improvement thereof.” Judge Rich’s ellipses omitted the statutory language “new and useful,” which appears twice in § 101. As he explained, “the invention is not examined under that statute for novelty because that is not the statutory scheme of things or the long-established administrative practice.” Instead, the invention, whether new or old, passes through the first door, to be examined for novelty at the second door under the standards set forth in § 102. To reject a claim for lack of novelty under § 101 rather than § 102 “is confusing and therefore bad law.”<sup>84</sup> In contrast to his tone of gentle condescension toward the Supreme Court for confusing the issues of patent-eligibility and patent-worthiness in *Parker v. Flook*, Judge Rich excoriated the Solicitor General for having done the same thing in its briefs, “badly and with a seeming sense of purpose.”<sup>85</sup>

Turning to the assigned task on remand of determining what light the Supreme Court’s opinion in *Parker v. Flook* shed on the issue in *Bergy* and *Chakrabarty*, Judge Rich concluded that the only thing the three cases had in common is that they all involved § 101. He noted that:

*Flook* was about the patentability of computer programs as “processes,” not about the patentability of living subject matter as “manufactures” or “compositions of matter.” Nor did the Court’s review of “hornbook law” concerning the nonpatentability of “principles, laws of nature, mental processes, intellectual concepts, ideas, natural phenomena, mathematical formulae, methods of calculation, fundamental truths, original causes, motives, the Pythagorean theorem, and . . . computer-implementable method claims . . .” have any application to the *Bergy* and *Chakrabarty* appeals, which “do not involve an attempt to patent any of these things.”<sup>86</sup>

On two final points, Judge Rich was not content to simply distinguish *Flook* from the cases before him, but felt the need to set the Supreme Court straight. First was the statement in *Flook*, relying on the authority of *Funk v. Kalo*, that a mathematical formula, like a law of nature, must be deemed to be “a familiar part of the prior art”—“even when it was not familiar, was not prior, was discovered by the applicant

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<sup>84</sup> *Bergy* at 961.

<sup>85</sup> *Id.* Judge Rich characterized as “subversive nonsense” the Solicitor General’s argument that the opening phrase, “Whoever invents or discovers . . .” continues in effect the prior judicial standard of “invention” as a requirement of § 101. *Id.* at 963.

<sup>86</sup> *Id.* at 965.

for patent, was novel at the time he discovered it, and was useful.”<sup>87</sup> Although insisting that “the foregoing novel principle has no applicability whatever” to the appeals before him, Judge Rich also warned that the Supreme Court’s approach “gives to the term ‘prior art,’ which is a very important term of art in patent law, . . . an entirely new dimension with consequences of unforeseeable magnitude.”<sup>88</sup> Second was Justice Stevens’s concluding observation, relying on the authority of *Deepsouth Packing Co. v. Laitram Corp.*,<sup>89</sup> that the courts should proceed cautiously when “asked to extend patent rights into areas wholly unforeseen by Congress.”<sup>90</sup> Peering behind the *Flook* opinion to the *Deepsouth* case, Judge Rich thought that what had made it appropriate for the Court in *Deepsouth* to await further guidance from Congress was that it was asked to overturn a long line of prior decisions. By contrast, Judge Rich observed that the *Bergy* and *Chakrabarty* cases raised an issue of first impression, which the courts could resolve on their own without awaiting any signal from Congress.<sup>91</sup> He returned to this theme at the end of the opinion, turning the charge of unauthorized lawmaking back on the PTO:

Faced with the necessity of rendering a decision one way or the other on whether these inventions are encompassed by § 101, there being no prior decisions to guide us, we merely carry out our normal judicial function in deciding to say yes rather than no. . . . Rather, it seems to us, it is the PTO, not this court, that is attempting to legislate. It may have reasons for not wanting to examine the appealed claims for patentability under §§ 102 and 103, but if so, it has not revealed them . . . For whatever reason, it decided to reject, first on one ground and then on another, and then set out, lawyer-like, to devise unduly exaggerated justifications spiced with bits and pieces from wholly unrelated plant patent legislation from nearly half a century ago. . . . “We should not read into the patent laws limitations and conditions which the legislature has not expressed.”<sup>92</sup>

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<sup>87</sup> *Id.* at 965–66 (“This gives to the term ‘prior art,’ which is a very important term of art in patent law, particularly in the application of § 103, an entirely new dimension with consequences of unforeseeable magnitude. . . . The potential for great harm to the incentives of the patent system is apparent.’”).

<sup>88</sup> *Id.*

<sup>89</sup> 406 U.S. 518 (1972).

<sup>90</sup> *Parker v. Flook*, 437 U.S. 584, 596 (1978).

<sup>91</sup> 596 F.2d at 966–67.

<sup>92</sup> *Id.* at 987–88 (quoting from *U.S. v. Dubilier Condenser Corp.*, 289 U.S. 178, 199 (1933)).

Judge Rich's opinion on remand offered substantially the same analysis as his original opinions for the CCPA in *Bergy* and *Chakrabarty*. But the decision on remand picked up an additional vote from Judge Baldwin, who had dissented the first time around in both cases.<sup>93</sup> He wrote a separate concurring opinion disagreeing with Judge Rich's conclusion that *Parker v. Flook* had no bearing on these appeals, and then offered a painstaking analysis of Supreme Court precedents that had excluded certain categories of subject matter from patent protection notwithstanding that they fell within "the dictionary definitions of process, manufacture or composition of matter:"

The common thread throughout these cases is that claims which directly or indirectly preempt natural laws or phenomena are proscribed, whereas claims which merely utilize natural phenomena via explicitly recited manufactures, compositions of matter or processes to accomplish new and useful end results define statutory inventions.<sup>94</sup>

Because he concluded that the claims before the court "do not reach out to encompass natural phenomena . . . but rather recite only non-naturally occurring compositions of matter that are but single tools for utilizing natural phenomena in producing new and useful end results," he voted with the majority to reverse the rejections.<sup>95</sup> The sole remaining dissenter was Judge Miller, who chastised the majority for concentrating on "literal statements" in *Parker v. Flook* while ignoring the thrust of the Court's admonition to await a clear signal from Congress when there is a basis for substantial doubt as to its intent.<sup>96</sup>

### Back to the Supreme Court

By this point the scientific and commercial significance of the controversy over patenting life was manifest. As concerns about the hazards of gene-splicing were subsiding among scientists,<sup>97</sup> researchers had successfully used recombinant DNA technology to clone medically

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<sup>93</sup> 596 F.2d 952, 988 (Baldwin, J. concurring).

<sup>94</sup> *Id.*

<sup>95</sup> *Id.* at 997. Judge Baldwin also dismissed the argument that the decision would inevitably lead to the patenting of higher life forms with the prediction that inventors would find it too difficult to comply with the disclosure requirements of § 112 of the Patent Act for higher organisms. *Id.* at n.7.

<sup>96</sup> 596 F.2d 952, 999 (Miller, J., dissenting).

<sup>97</sup> After initially imposing stringent guidelines on the use of government funds in recombinant DNA research, 41 Fed. Reg. 27902 (Jul. 7, 1976), the National Institutes of Health relaxed the restrictions considerably 2 ½ years later after preliminary experience produced no evidence of illness or other harm. 43 Fed. Reg. 60080 (Dec. 22, 1978).



important genes in microorganisms.<sup>98</sup> New companies were forming to develop promising therapies out of these discoveries, raising capital from investors who hoped to earn a return on their investments.<sup>99</sup> Both private firms and universities engaged in biotechnology research looked to patents as a means of capturing the value of the new technology, and took note of the *Chakrabarty* and *Bergy* cases.

While the cases were before the CCPA on remand from the Supreme Court, the University of California, the American Patent Law Association, and Genentech filed amicus briefs on behalf of the patent applicants.<sup>100</sup> By the time the cases reached the Supreme Court again, these amici were joined by the New York Patent Law Association, the Pharmaceutical Manufacturers Association, the American Society for Microbiology, the American Society of Biological Chemists, the Association of American Medical Colleges, the American Council on Education, and the California Institute of Technology, as well as several eminent scientists, all arguing in favor of patent protection. Indeed, according to historian Daniel Kevles, by this point many people within the PTO favored patent protection for living organisms, including the new Commissioner, Donald Banner, who thought the CCPA decision was correct and was not inclined to seek Supreme Court review.<sup>101</sup> Others within the PTO favored taking the case to the Supreme Court in the hope of getting an affirmation that would give biotechnology investors greater assurance of the validity of their patents, while the Solicitor General of the United States favored reversal.<sup>102</sup> The government filed for *certiorari* in both cases, but after the petition was granted, the patent applicant in *Bergy* voluntarily canceled its claims to the purified microorganism, leading the Supreme Court to remand with instructions to dismiss *Bergy* as moot.<sup>103</sup> As a consequence (indeed, perhaps by design),<sup>104</sup> the Supreme Court was left

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<sup>98</sup> See, e.g., K. Itakura et al., *Expression in Escherichia coli of a chemically synthesized gene for the hormone somatostatin*; 198 SCIENCE 1056-63 (1977); D. Goeddel et al., *Expression in Escherichia coli of chemically synthesized genes for human insulin*, 76 PROC NATL ACAD SCI 106-110 (1979); D. Goeddel et al., *Direct expression in Escherichia coli of a DNA sequence coding for human growth hormone*, 281 NATURE 544-48 (1979).

<sup>99</sup> See, e.g., R. Reinhold, *There's Gold in Them Thar Recombinant Genetic Bits*, N.Y. TIMES, June 22, 1980, sec. 4, p.8, col. 3; *Where genetic engineering will change industry*, BUS. WK., Oct. 22, 1979, at 160.

<sup>100</sup> *In re Bergy*, 596 F.2d at 957.

<sup>101</sup> Kevles, *supra* note 26, at 126.

<sup>102</sup> *Id.* at 123, 126-27.

<sup>103</sup> *Diamond v. Chakrabarty*, 444 U.S. 1028 (1980) (vacating judgment in *In re Bergy* and remanding with directions to dismiss as moot).

<sup>104</sup> According to Professor Kevles, *Bergy's* lawyer believed that *Chakrabarty* had a stronger case, and thought it more likely that the Supreme Court would uphold the

to consider the patentability of life forms only in the more compelling context of the human-modified organism claimed in *Chakrabarty*.

If the PTO Commissioner was an ambivalent petitioner before the Supreme Court, the Petitioner's Brief did not betray it.<sup>105</sup> Characterizing the question presented as whether a living organism is patentable subject matter, the brief cited venerable Supreme Court precedent requiring that "the patent laws . . . be strictly construed in light of the basic national economic policy against monopoly, and in order to preserve to Congress decisions concerning extension of the patent laws into new areas."<sup>106</sup> According to the petitioner, "it was generally assumed by the legal profession, writers on the subject, and Congress" that living organisms are not patentable, and Congress had acted on that assumption in passing the Plant Patent Act in 1930 and the Plant Variety Protection Act in 1970.<sup>107</sup> Congress, but not the courts, could adapt the terms of protection to suit the attributes of living subject matter, as it had done in those prior acts, and could decide what weight to attach to perceptions of ethical problems and public health risks associated with genetic engineering.<sup>108</sup> The brief made no mention of *Funk v. Kalo* or the products of nature doctrine.

Chakrabarty disputed that allowance of his claim would extend the patent laws into new areas,<sup>109</sup> counting over sixty issued U.S. patents claiming living subject matter and identifying official PTO classes and subclasses to deal with such patents.<sup>110</sup> Highlighting a passage from the legislative history of the Patent Act, Chakrabarty urged that a patentable manufacture "may include anything under the sun that is made by man,"<sup>111</sup> and went on to distinguish his engineered organism from the relatively unchanged living materials that had been denied patent protection in past judicial decisions. He concluded that "[i]f the Government

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patentability of living subject matter if the only case before it were *Chakrabarty* than if it were deciding both cases together. Kevles, *supra* note 26, at 127.

<sup>105</sup> See Brief for Petitioner on Writ of Certiorari to the United States Court of Customs and Patent Appeals, *Diamond v. Chakrabarty* (filed Jan. 4, 1980) (available from Lexis-Nexis).

<sup>106</sup> *Id.*, text preceding note 9.

<sup>107</sup> *Id.*, text at note 9.

<sup>108</sup> *Id.*, text at notes 14-23.

<sup>109</sup> See Brief for Respondent On Writ of Certiorari to the United States Court of Customs and Patent Appeals, *Diamond v. Chakrabarty* (filed Jan. 29, 1980) (available from Lexis-Nexis).

<sup>110</sup> *Id.* text at notes 9-10.

<sup>111</sup> *Id.* at note 22 (quoting H.R. Rep. No. 1923, 82d Cong., 2d Sess. (1952), p.6; S. Rep. No. 1979 (1952), U.S. Code, Cong. and Admin. News, p. 2399).

wishes to reverse its policy, it should address its desires to the Congress, which can legislate an exclusion, if that is found to be required by the public interest.”

Chakrabarty's numerous *amici*, including elite scientists, universities, and scientific societies, explained to the Court the sophisticated human intervention involved in the new biotechnology and argued that a *per se* rule excluding living things from patentability would discourage the commercial development of important scientific advances.<sup>112</sup> Some of the briefs urged that a distinction between living and nonliving subject matter was not only unprecedented as a matter of patent law, but unworkable and meaningless from a scientific perspective.<sup>113</sup>

Only one *amicus curiae* filed a brief in support of the government opposing patent protection for living subject matter on the merits—the Peoples Business Commission, a non-profit educational foundation formed by genetic engineering critic Jeremy Rifkin. That brief paradoxically echoed the arguments in favor of patent protection for living organisms, noting that such patents “would significantly contribute to the profit potential of the genetic industry, thus generating a greater momentum in research and development of genetic engineering technologies” leading to a “rapid proliferation of genetic techniques . . . in many other aspects of the nation's economic life.”<sup>114</sup> Reading these arguments today, it takes some imagination to reconstruct the prevailing anxiety about genetic engineering that would lead the authors to expect these incentive effects to be counted as a reason to *exclude* living subject matter from patent protection.

The Supreme Court ultimately affirmed the CCPA by a 5–4 vote, revealing a significant shift in the balance of views on the Court since the 6–3 decision just two years earlier in *Parker v. Flook*. The *Chakrabarty* majority included Justice Stevens, who had authored the majority

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<sup>112</sup> The arguments advanced in the briefs are summarized in Kevles, *supra* note 26 at 127–31.

<sup>113</sup> See, e.g., Brief on Behalf of Dr. Leroy E. Hood, Dr. Thomas P. Maniatis, Dr. David S. Eisenberg, The American Society Of Biological Chemists, The Association Of American Medical Colleges, The California Institute of Technology, The American Council On Education As Amici Curiae at 12 (filed Jan. 26, 1980) (Westlaw Supreme Court Briefs file) (“There is no distinct line between life and non-life. The prevailing view among scientists is that the essential characteristic of ‘living’ subject matter is nothing more than its complexity.”); Brief of Dr. George Pieczenik as Amicus Curiae at 3 (filed Jan. 29, 1980) (Westlaw Supreme Court Briefs file) (“The distinction between living and non-living matter has no real meaning in relation to this technology. . . . To attempt to separate patentable and unpatentable subject matter on the basis of such a concept is to invite confusion in the art, to ignore existing law and to ignore scientific reality.”).

<sup>114</sup> Brief on Behalf of the People's Business Commission, Amicus Curiae at 3 (filed Dec. 13, 1979) (Westlaw Supreme Court Briefs file).

opinion denying patent protection in *Flook*, and Justice Blackmun, who had joined in that opinion, as well as the three *Flook* dissenters, Justices Stewart and Rehnquist and Chief Justice Burger. Justice Stevens's opinion for the *Flook* majority and Chief Justice Burger's opinion for the *Chakrabarty* majority took strikingly different approaches to the proper construction of section 101 of the Patent Act. Whereas the *Flook* majority had insisted that the "plain language" of section 101 did not answer the question of what kind of "discoveries" the statute was enacted to protect,<sup>115</sup> the *Chakrabarty* majority rested heavily on the plain language of the statute, proclaiming that "courts 'should not read into the patent laws limitations and conditions which the legislature has not expressed.'"<sup>116</sup> The *Flook* majority had warned that "we must proceed cautiously when we are asked to extend patent rights into areas wholly unforeseen by Congress."<sup>117</sup> Two years later, the *Chakrabarty* majority balked at applying this principle to preclude patenting of living subject matter, quipping that "[a] rule that unanticipated inventions are without protection would conflict with the core concept of the patent law that anticipation undermines patentability" and insisting that "Congress employed broad general language in drafting § 101 precisely because such inventions are often unforeseeable."<sup>118</sup> Both opinions acknowledged that it was up to Congress, and not the courts, to set the boundaries of patent eligibility. But the *Flook* majority thought the PTO and the courts should await further clarification from Congress before allowing patent protection for computer-implemented inventions of the sort at issue in that case, while the *Chakrabarty* majority, believing that Congress had already broadly authorized patent protection for "anything under the sun that is made by man," thought that until Congress saw fit to amend the statute, "this Court must construe the language of § 101 as it is."<sup>119</sup>

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<sup>115</sup> *Parker v. Flook*, 437 U.S. at 588, 593.

<sup>116</sup> *Diamond v. Chakrabarty*, 447 U.S. at 308.

<sup>117</sup> 437 U.S. at 596.

<sup>118</sup> *Diamond v. Chakrabarty*, 447 U.S. at 315-16.

<sup>119</sup> *Id.* at 318. One could reconcile the two decisions as a formal matter on the ground that in *Chakrabarty* the government was proposing a new limitation on patent eligibility (an exclusion for living subject matter) that had never previously been articulated in the case law, while in *Flook* it was relying upon a longstanding limitation (an exclusion for mathematical algorithms) that was well established in prior cases. If one imagines that Congress scrutinizes judicial opinions and enacts new legislation when it is unhappy with the directions of the case law, perhaps it makes sense for the Court to await guidance from Congress before creating a new judicial limitation (as it did in *Chakrabarty*), while retaining in effect time-honored judicial limitations that Congress has had plenty of time to correct (such as the limitation at issue in *Flook*). Indeed, perhaps this explains why Justice Stevens was willing to join the expansive majority opinion in *Chakrabarty*, although he had

The phrase “anything under the sun that is made by man” has been much quoted in subsequent judicial decisions as supporting an expansive interpretation of the scope of § 101.<sup>120</sup> But the expansive words “anything under the sun” are qualified by the restrictive condition “that is made by man.” For the *Chakrabarty* majority, this restrictive condition captured the difference between Chakrabarty’s microorganism and the kinds of discoveries that had previously been excluded from patent protection as “laws of nature, physical phenomena, and abstract ideas.”<sup>121</sup> The Court saw the same distinction lurking in the legislative history of the Plant Patent Act:

Congress . . . recognized that the relevant distinction was not between living and inanimate things, but between products of nature, whether living or not, and human-made inventions.<sup>122</sup>

Although the government never argued that Chakrabarty’s organism was a product of nature, Justice Burger nonetheless explained at some length why it was not, suggesting that the government’s concession on this point made the outcome of the case a foregone conclusion. The very first sentence of the opinion characterized the issue before the court as “whether a live, *human-made* micro-organism is patentable subject matter under 35 U.S.C. § 101.”<sup>123</sup> Later, the majority emphatically distinguished Chakrabarty’s microorganism from the unpatentable discovery in *Funk v. Kalo*:

There, the patentee had discovered that there existed in nature certain species of root-nodule bacteria which did not exert a mutually inhibitive effect on each other. He used that discovery to produce a mixed culture capable of inoculating the seeds of leguminous plants. . . . Here, by contrast, the patentee has produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility. His discovery is not nature’s handiwork, but his own; accordingly it is patentable subject matter under § 101.<sup>124</sup>

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opposed patent protection for computer-implemented inventions just two years earlier when he authored the majority in *Parker v. Flook* and did so again one year later when he authored the dissent in *Diamond v. Diehr*.

<sup>120</sup> *Diamond v. Diehr*, 450 U.S. 175, 182 (1981); *J.E.M. Ag Supply v. Pioneer Hi-Bred*, 534 U.S. 124, 130 (2001); *State St. Bank & Trust v. Signature Financial Group*, 149 F.3d 1368, 1373 (Fed. Cir. 1998), *cert. denied*, 525 U.S. 1093 (1999).

<sup>121</sup> *Diamond v. Chakrabarty*, 447 U.S. at 309.

<sup>122</sup> *Id.* at 313.

<sup>123</sup> *Id.* at 305 (emphasis added).

<sup>124</sup> *Id.* at 310.

In other words, once it was conceded that the microorganism was not a product of nature, the invention had passed the test of § 101.

### Beyond Chakrabarty

Although the Supreme Court recognized in *Chakrabarty*, as it had in prior decisions, that Congress has the authority to set the rules for determining what may be patented, *Chakrabarty* nonetheless seemed to represent a shift in the default rules that apply in the face of Congressional inaction.<sup>125</sup> Whereas *Flook*, by denying protection, had placed the burden of inertia on those who seek protection for new fields of technology to approach Congress, *Chakrabarty*, by granting protection, placed the burden of inertia on those who opposed it. This shift has had a number of important consequences.

First, it immediately stemmed the flow of cases involving the scope of § 101 into the courts. The decision in *Chakrabarty* signaled to the PTO that the Supreme Court was unlikely to back them up in future disputes with the CCPA (and, later, the Federal Circuit) over interpretation of the scope of patent eligible subject matter. The PTO promptly became less skeptical about the patent eligibility of new categories subject matter, holding, for example, that plants<sup>126</sup> and animals<sup>127</sup> were eligible for protection under § 101 and thereby avoiding the occasion for judicial review of the soundness of its § 101 rejections. When the PTO rejects patent claims, applicants may appeal their decisions immediately, but when the PTO allows claims, the courts have no occasion to consider the correctness of the allowances until an infringement defendant challenges the validity of an issued patent. A defendant may avoid infringement liability by proving that a patent is invalid by clear and convincing evidence,<sup>128</sup> and occasionally defendants have argued that an issued patent is invalid under § 101.<sup>129</sup> But because infringement defendants are typically commercial competitors of the plaintiffs who hold patents of

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<sup>125</sup> The Supreme Court had once before authorized protection, over a vigorous dissent, for subject matter that Congress had thus far declined to protect in the case of *International News Service v. Associated Press*, 248 U.S. 215 (1918), affirming a lower court remedy for common law "misappropriation" of news stories that the parties conceded could not be protected under federal copyright law.

<sup>126</sup> *In re Hibberd*, 227 U.S.P.Q. (BNA) 443 (Bd. Pat. App. & Int. 1985) (reversing examiner's rejection for lack of eligible subject matter of patent claims to seeds and plants in reliance on *Diamond v. Chakrabarty*).

<sup>127</sup> *Ex parte Allen*, 2 U.S.P.Q.2d (BNA) 1425 (Bd. Pat. App. & Int. 1987) (reversing examiner's rejection for lack of eligible subject matter of patent claims to oysters).

<sup>128</sup> See *Cardinal Chemical Co. v. Morton Int'l, Inc.*, 508 U.S. 83 (1993).

<sup>129</sup> *E.g.*, *State St. Bank & Trust v. Signature Financial Group*, 149 F.3d 1368, 1373 (Fed. Cir. 1998), *cert. denied*, 525 U.S. 1093 (1999); *J.E.M. Ag Supply v. Pioneer Hi-Bred*, 534 U.S. 124, 130 (2001).

their own on similar subject matter, they are more likely to challenge the patents on grounds that are specific to the particular patents in suit (such as anticipation or obviousness in light of the prior art) rather than on broader grounds (such as lack of patentable subject matter) that might categorically invalidate the patents that they own along with the patents that they are charged with infringing. Even when infringement defendants are willing to challenge the patent eligibility of an invention, the issue is unlikely to come before the courts in this context until years after the patent was first issued. Meanwhile, as the PTO continues to issue patents in a field, the expectation interest of firms in the continuing availability of patents for their inventions grows, making it harder for courts to upset those interests by announcing a categorical exclusion from patent eligibility.

Second, although the Court purported to address only a narrow issue of statutory interpretation concerning whether Chakrabarty's microorganism was eligible for patent protection, it ultimately embraced a very broad rule of patentability for "everything under the sun that is made by man," leaving little room to distinguish *Chakrabarty* in subsequent cases. For this reason, *Chakrabarty* has become a standard citation for the patentability of subject matter ranging from computer-implemented algorithms<sup>130</sup> and business methods<sup>131</sup> to plants.<sup>132</sup> Those who believe the patent system should exclude any categories of human innovation from its reach have little hope of prevailing in the courts, even if they get sued for patent infringement,<sup>133</sup> but must make their case before Congress. The result has been a stunning expansion in the kinds of innovations that are brought before the PTO, including new sports moves, games, cooking recipes, and even the technology of legal practice.<sup>134</sup>

Third, the burden of persuading Congress to change the patent laws has proven to be a heavy one, especially in industries where patent holders have a strong interest in maintaining the status quo and are thus well motivated to outmaneuver and outspend their anti-patent adversaries. For example, although religious groups and others opposed

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<sup>130</sup> *AT & T v. Excel Communications*, 172 F.3d 1352, 1355 (Fed. Cir.), cert. denied, 528 U.S. 946 (1999).

<sup>131</sup> *State St. Bank & Trust v. Signature Financial Group*, 149 F.3d 1368, 1373 (Fed. Cir. 1998), cert. denied, 525 U.S. 1093 (1999).

<sup>132</sup> *J.E.M. Ag Supply v. Pioneer Hi-Bred*, 534 U.S. 124, 130 (2001).

<sup>133</sup> Those who wish to challenge the issuance of patents that they are not infringing face the additional burden of persuading the courts that they have standing to litigate the issue. See, e.g., *Animal Legal Defense Fund v. Quigg*, 932 F.2d 920 (Fed. Cir. 1991) (dismissing challenge to issuance of patents on animals for lack of standing).

<sup>134</sup> Recent examples may be found in ROBERT P. MERGES & JOHN F. DUFFY, *PATENT LAW & POLICY: CASES AND MATERIALS* at 206-08 (3d ed. 2002).

to the patenting of animals as a matter of principle were able to get some members of Congress to hold hearings on the topic,<sup>135</sup> they ultimately failed to get any legislation passed. Opposition to patents on DNA sequences has followed a similar course in the legislative arena.<sup>136</sup>

In 1980, the Supreme Court assumed that Congress was “free to amend § 101 so as to exclude from patent protection organisms produced by genetic engineering” or “to craft a statute specifically designed for such living things.”<sup>137</sup> Even at the time, such legislative action may have been improbable.<sup>138</sup> Twenty-five years later, the only special rules that Congress has enacted for biotechnology patents have been provisions that the biotechnology industry has favored.<sup>139</sup>

## Conclusion

The decision of the Supreme Court in *Diamond v. Chakrabarty* was a watershed moment not just for the biotechnology industry, but also for

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<sup>135</sup> *E.g.*, Patents and the Constitution: Transgenic Animals: Hearings Before the Subcomm. on Courts, Civil Liberties and the Administration of Justice of the House Comm. on the Judiciary, 100<sup>th</sup> Cong., 1<sup>st</sup> Sess. (1987).

<sup>136</sup> *E.g.*, Gene Patents and Other Genomic Inventions: Hearing Before the Subcomm. on Courts and Intell. Prop. of the House Comm. on the Judiciary, 106<sup>th</sup> Cong. (2000).

On the other hand, the American Medical Association effectively lobbied Congress for relief from remedies for infringement of patents on medical and surgical methods. P.L. No. 104-208, Div. A, Title I, § 101(a), codified at 35 U.S.C. § 287(c). For an account of the legislative process by which this provision was enacted, see Chris J. Katopis, *Patients v. Patents?: Policy Implications of Recent Patent Legislation*, 71 ST JOHN'S L. REV. 329, 331-38 (1997).

More recently, following the decision of the Federal Circuit to allow patents on business methods in *State St. Bank*, Congress passed legislation protecting prior users of subsequently patented business methods from infringement liability. P.L. No. 106-113, Div. B, § 1000(a)(9), 113 Stat. 1536, codified at 35 U.S.C. § 273.

Neither of these legislative initiatives altered the range of subject matter eligible for patent protection under § 101.

<sup>137</sup> *Diamond v. Chakrabarty*, 447 U.S. at 318.

<sup>138</sup> Today, it might well place the U.S. in violation of its treaty obligations. The GATT-TRIPS agreement, to which the U.S. acceded in 1995, prohibits members from discriminating in the provision of patent protection on the basis of field of technology. In fact, although the U.S. patent system generally applies a unitary set of rules to inventions in all fields, the Patent Act has some field-specific provisions, some of which Congress has enacted since the TRIPS agreement took effect.

<sup>139</sup> *See, e.g.*, 35 U.S.C. § 103(b) (permitting the patenting of a biotechnological process using or resulting in a composition of matter that is novel and nonobvious, notwithstanding that the process might not otherwise be deemed nonobvious). *See also*, 35 U.S.C. § 271(g) (defining as patent infringement the importation into the U.S. of a product made abroad by a U.S.-patented process, a change in the law favored by the biotechnology industry).



the ongoing struggle between champions of an expansive patent system on the CCPA and the skeptics on the Supreme Court. As predicted by both proponents and opponents of patents on living organisms, investment in biotechnology R & D has flourished in the wake of *Diamond v. Chakrabarty*. But the full consequences of the expansive approach to patent eligibility endorsed by the *Chakrabarty* majority continue to be felt far beyond the biotechnology industry. Five years after the departure from the Supreme Court of Justice Douglas, the *Chakrabarty* decision marked the beginning of the end of the Court's skeptical period. Thereafter, it would be up to the CCPA and the Federal Circuit, absent explicit restrictions from Congress, to decide just how expansive the subject matter boundaries of the patent system are. By the time of Judge Rich's death nearly twenty years later, the Federal Circuit had not only refrained from adopting new judge-made limitations on patent eligibility, but had retreated from limitations announced in prior caselaw.<sup>140</sup> The Supreme Court has not seen fit to reverse, and Congress has not seen fit to intervene. A quarter century ago it was unclear whether the subject matter boundaries of the patent system were expansive enough to embrace biotechnology and information technology. Today, it is not clear whether the patent system has any subject matter boundaries at all.

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<sup>140</sup> *E.g.*, *In re Lowry*, 32 F.3d 1579 (Fed. Cir. 1994) (overturning "printed matter" rejection); *State St. Bank & Trust v. Signature Financial Group*, 149 F.3d 1368 (Fed. Cir. 1998), *cert. denied*, 525 U.S. 1093 (1999) (reversing holding of invalidity based on exclusions for mathematical algorithms and business methods); *AT & T v. Excel Communications*, 172 F.3d 1352 (Fed. Cir.), *cert. denied*, 528 U.S. 946 (1999) (reversing holding of invalidity based on exclusions of mathematical algorithms and intangible processes).